

§ 878.5360

hair shaft, under the skin, and into the dermal papilla. The electric current may be high-frequency AC current, high-frequency AC combined with DC current, or DC current only.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

§ 878.5360 Tweezer-type epilator.

(a) *Identification*. The tweezer-type epilator is an electrical device intended to remove hair. The energy provided at the tip of the tweezer used to remove hair may be radio frequency, galvanic (direct current), or a combination of radio frequency and galvanic energy.

(b) *Classification*. Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[63 FR 57060, Oct. 26, 1998]

§ 878.5650 Topical oxygen chamber for extremities.

(a) *Identification*. A topical oxygen chamber for extremities is a device intended to surround hermetically a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers or bed sores.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See § 878.3.

§ 878.5900 Nonpneumatic tourniquet.

(a) *Identification*. A nonpneumatic tourniquet is a device consisting of a strap or tubing intended to be wrapped around a patient's limb and tightened to reduce circulation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

21 CFR Ch. I (4–1–11 Edition)

subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13828, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.5910 Pneumatic tourniquet.

(a) *Identification*. A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit, connecting tubing, and an inflatable cuff. The cuff is intended to be wrapped around a patient's limb and inflated to reduce or totally occlude circulation during surgery.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart A—General Provisions

Sec.

880.1 Scope.

880.3 Effective dates of requirement for premarket approval.

880.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B [Reserved]

Subpart C—General Hospital and Personal Use Monitoring Devices

880.2200 Liquid crystal forehead temperature strip.

880.2400 Bed-patient monitor.

880.2420 Electronic monitor for gravity flow infusion systems.

880.2460 Electrically powered spinal fluid pressure monitor.

880.2500 Spinal fluid manometer.

880.2700 Stand-on patient scale.

880.2720 Patient scale.

880.2740 Surgical sponge scale.

880.2800 Sterilization process indicator.

880.2900 Clinical color change thermometer.

880.2910 Clinical electronic thermometer.

880.2920 Clinical mercury thermometer.

880.2930 Apgar timer.

Subparts D–E [Reserved]